

Exhibit 1

Email Activity

From: Paul Hardy [REDACTED]
 Date: 1/29/09
 To: roycejoanne [REDACTED]
 CC:
 BCC:
 Subject: A concern of mine

Thank You Joanne for your response. I guess my issue when reading his article is that I do not want the focus to shift off topic and then there be a question as to whether the "FDA 9" leaked confidential information to the press without going to Congress first and then everything out there (i.e. article about the contact from the Fuji Congressman to Donna-Bea Tillman) would look like it is invalid because it may have the appearance that it was obtained under a cloud of suspicion. However, I do appreciate your re-assurance.

Thanks,
 P.J.

- Show quoted text -

On Thu, Jan 29, 2009 at 10:58 AM, Joanne Royce [REDACTED] wrote:

Hi P.J., You are generally correct - it is rarely a crime to reveal documents to Congress - unless they are stolen or classified. However, Gardiner was also correct - it can be a crime for agency employees to reveal certain documents to the public - he should perhaps have qualified his statement by saying it is a crime to release to the public but not to Congress. However, you and your colleagues have committed no crime and it is a retaliatory investigation by OCI which should be stopped. We're working to get the investigation stopped. Thank you for your continued service to the consumers, Joanne

--- On Thu, 1/29/09, Paul Hardy <[REDACTED]> wrote:

From: Paul Hardy [REDACTED]
 Subject: A concern of mine
 To: "Joanne Royce" <[REDACTED]>
 Cc: "R Smith" <[REDACTED]>
 Date: Thursday, January 29, 2009, 12:12 AM

Hi Joanne,

This is P.J. Hardy. We met several weeks ago in the Rayburn building to talk with Rep. Waxman's staff about the things going on at the FDA. I know you have been primarily dealing with Robert and I want to say how much I appreciate your continued work in all of this. I happened to see a story done by Mr. Gardiner Harris tonight about us writing a letter to President Obama telling him how we believed the FDA had opened a criminal investigation on us. While I agree with the majority of his article, there is one part that really concerns me. He says:

"It can be a crime for agency employees to reveal documents or information considered confidential by companies seeking agency approval for medical products." If I am not mistaken, it is not a crime to provide information to the Congress about potential misconduct

by another Agency employee. Maybe I have been misinformed this whole time. However, it is my opinion that Mr. Harris needs to run a correction in the Times clarifying this statement. Perhaps you could provide me the legal opinion about his statement.

Thanks,
P.J. Hardy

Email Activity

From: Joanne Royce [REDACTED]
 Date: 1/29/09
 To: [REDACTED]
 CC:
 BCC:
 Subject: A concern of mine

P.J.: that is precisely the legal position that our Committee takes, i.e. that even confidential and confidential business information submitted to Congress is legal. Nevertheless, it is a debatable legal question - i.e., it hasn't been finally decided in the courts. But I agree with Robert - you guys didn't even provide confidential business information to Congress. It is a common retaliatory tactic by agencies and IG's to open criminal investigations into whistleblowers in order to intimidate them. Joanne

--- On Thu, 1/29/09, Paul Hardy <[REDACTED]> wrote:

From: Paul Hardy [REDACTED]
 Subject: Re: A concern of mine
 To: "R Smith" <[REDACTED]>
 Cc: "Joanne Royce" <[REDACTED]>
 Date: Thursday, January 29, 2009, 8:54 AM
 - Show quoted text -

Joanne,
 I know you have not responded to my first e-mail, but I have another thought as well. If there was confidential information submitted to the Congress (not saying any of the information submitted has been since it mainly showed the corruption by Agency managers) is it in a sense "covered" because the Energy and Commerce Committee started an investigation in November? and thus any information supplied to Congress is part of the investigation into claims of corruption and/or abuse of power?
 -P.J.

On Thu, Jan 29, 2009 at 12:38 AM, R Smith <[REDACTED]> wrote:

Hi Joanne and PJ: PJ, you are correct. Mr. Harris does not give the statutory citation. Clearly, all FDA employees are permitted to disclose information to Congress. Mr. Harris should make that clear. Presumably he refers to 18 USC 1905. Even under 18 USC 1905, the disclosure would have to be of trade secrets (or something of the like). I don't think any such material has even been disclosed to Congress (although it could be). Even under 18 USC 1905, "Any information that is discoverable under the Federal Rules of Civil Procedure cannot be said to be confidential information under 18 USCS 1905, even if exempt from disclosure to public under Freedom of Information Act (5 USCS § 552(b)(1)-(9)). Pleasant Hill Bank v United States (1973, WD Mo) 58 FRD 97, 17 FR Serv 2d 897."

It is a bit of a stretch to even suggest that we could have committed a crime. But I guess it makes the story more interesting. I guess it shows how outrageous it is that the Agency could even suggest such a thing. Maybe that was is point.

But, hey, what do I know, after all I am just one of the dissidents.

On Thu, Jan 29, 2009 at 12:12 AM, Paul Hardy <[REDACTED]> wrote:

Hi Joanne,

This is P.J. Hardy. We met several weeks ago in the Rayburn building to talk with Rep. Waxman's staff about the things going on at the FDA. I know you have been primarily dealing with Robert and I want to say how much I appreciate your continued work in all of this. I happened to see a story done by Mr. Gardiner Harris tonight about us writing a letter to President Obama telling him how we believed the FDA how opened a criminal investigation on us. While I agree with the majority of his article, there is one part that really concerns me.

He says:

"It can be a crime for agency employees to reveal documents or information considered confidential by companies seeking agency approval for medical products." If I am not mistaken, it is not a crime to provide information to the Congress about potential misconduct by another Agency employee. Maybe I have been misinformed this whole time. However, it is my opinion that Mr. Harris needs to run a correction in the Times clarifying this statement. Perhaps you could provide me the legal opinion about his statement.

Thanks,
P.J. Hardy

and seeing. I remember you telling me how Kyle brought it up at a staff meeting and that things could change in the next couple of months (about people's contracts) and how this made you very upset. Perhaps I read into this wrong. But, I don't see how waiting for Kyle and Nick to maybe renew your contract brings you any more difficulty than you already have. They have made your life a living hell and I know you say now that you don't have to deal with Kyle and you deal with Nick, but if you think that somehow this is going to make everything great, I would say this is not true. And if they don't renew your contract then what? We are all in this together for better or worse and its not going to go away whether we like it or not.

Believe me I am not naive to think that Republicans taking over are going to fix anything at FDA. Everyone is corrupt, but in my opinion, we use that to our advantage. You had said that Sharfstein and Shuren are temporary, but does this mean that they should be allowed to wreak havoc in the meantime without ever being exposed for the true frauds that they are? Why shouldnt people like [REDACTED] ever have to answer for all the horrible things that they have done. I gave up on anything good at the FDA a long time ago when it was clear that nothing was going to change and now I am just trying to make the most money I can and I think Steve can help do that. I didn't write that e-mail so that Emilia would do something, she has shown she is utterly [REDACTED] for the longest time allowing the mayhem at FDA to continue in the face of overwhelming evidence, but its just for documentation.

Again, I am sorry and I won't mention you again without asking you. Your my commandant and I should have received the order.

Talk to you soon buddy,
P.J.

On Fri, Oct 15, 2010 at 2:20 PM, [REDACTED] wrote:
PJ,

Why you did not ask me if I agreed to be referred to or quoted in the email. Thank you for asking. I disagreed by doing such unless i consent and i do not for this time again. By doing what you do, you may bring difficulty to me more than you can think. Please do not bring up things about some else unless he or she agrees. I am pest off the least to say.

On Oct 15, 2010, at 0:33, Paul Hardy <[REDACTED]> wrote:

Hi Emilia,

Sorry it has been so long since we last spoke. But as you may be aware, the [REDACTED] into FDA.

The last time that Dr. Smith and I spoke to you we specifically raised the issue that the [REDACTED]

especially since their timeline of investigating the complaints turned out to exclude many critical events, including the retaliatory termination of Dr. Nicholas. We also raised with you that FDA was making false and misleading statements to the press about the (b) (6) (b) (7) (C) " and that FDA was falsely (b) (6) (b) (7) (C) " as exonerating FDA of any wrongdoing. We remain concerned that their (b) (6) (b) (7) (C) is doing great harm to the Public and has (and continues to do) great harm to us. You told us at the time that there was not much that your staff could do because the (b) (6) (b) (7) (C) " was already out there and would be difficult to get around. Now that (b) (6) (b) (7) (C) and the press have torn down that report and exposed it for the sham it was, and now that (b) (6) (b) (7) (C) has essentially admitted that their first investigation was a sham, (b) (6) (b) (7) (C) is somehow apparently planning to do yet (b) (6) (b) (7) (C). This is very suspect to say the least. Especially since (b) (6) (b) (7) (C) continues to portray the (b) (6) (b) (7) (C) as always intended to be only a (b) (6) (b) (7) (C). We have irrefutable proof that that is also a lie. The Minutes of the Meeting we had with (b) (6) (b) (7) (C) at the time the (b) (6) (b) (7) (C) started, by itself, shows that (b) (6) (b) (7) (C) is not being truthful.

The latest ploy by FDA has been to hide behind this (b) (6) (b) (7) (C) done by this firm called Kelly, Anderson and Associates (KAA). Their supposed role is to (b) (6) (b) (7) (C) (according to an internal email of Dr. Shuren) (b) (6) (b) (7) (C). " This completely contradicts e-mail correspondence that we have with Dr. Sharfstein and Shuren and also the minutes from a teleconference with (b) (6) (b) (7) (C) who was originally assigned to the case as he was to (b) (6) (b) (7) (C) including (b) (6) (b) (7) (C) and he stated to us in writing that if he was to find (b) (6) (b) (7) (C) he was going to (b) (6) (b) (7) (C) and continue with the non-criminal investigation. Suddenly, when (b) (6) (b) (7) (C), Robert and I had a conversation with you how we were concerned that the (b) (6) (b) (7) (C) was going to try and (b) (6) (b) (7) (C). It appears that our concerns were well-founded. According to Ruth McKee, CDRH Associate Director for Management, KAA has been given "authority" by HHS to (b) (6) (b) (7) (C). This is suspicious and fraudulent on its face because the (b) (6) (b) (7) (C) in February with no evidence (b) (6) (b) (7) (C). So how is KAA going to do (b) (6) (b) (7) (C) for them?

We have reached a point where this entire episode (e.g. (b) (6) (b) (7) (C) by (b) (6) (b) (7) (C) has, in fact, become a (b) (6) (b) (7) (C). As they say, the (b) (6) (b) (7) (C) is always worse than the (b) (6) (b) (7) (C). " Now that (b) (6) (b) (7) (C) and other congressional committees to basically acknowledge the first report was not properly done, they are going to all of sudden conduct a (b) (6) (b) (7) (C)? Without ever contacting (b) (6) (b) (7) (C).

It is a strange coincidence that [redacted] no longer works for [redacted] and [redacted] has been "transferred" to [redacted]. In addition, Dr. Smith was just recently contacted by one of the [redacted] that was a part of the [redacted] as he never [redacted] anything, how will we ever receive any justice? Furthermore, if FDA was really credible in pursuing these matters, they would have put out a public statement saying that they are outraged that [redacted] did not conduct the [redacted] that they asked for, but we know that they are covering up as well and have the documentation to prove this.

I am writing this e-mail asking for two things. First, we would greatly appreciate a letter and/or public statement from Senator Grassley calling for a special prosecutor to thoroughly investigate these matters because FDA and [redacted] can not possibly investigate themselves.

Second, we would greatly appreciate a letter from Senator Grassley to FDA demanding that they protect the remaining whistleblowers at FDA who have suffered severe retaliation and reprisal for trying to do their job and protect the public. [redacted]'s contract is up in a few weeks (and she has heard nothing). FDA is still trying to force [redacted] out of her job and none of the guilty managers in her EEO cases have been held publicly accountable (i.e. fired for breaking the law). [redacted]'s position is under grave threat (despite the fact that [redacted] is supposedly a "permanent" employee— and we are always told it is impossible to get rid of permanent employees— or does that only apply to corrupt permanent employee managers?)

I am happy to meet you at any time to ensure that the Public is protected, federal employees are protected, and there is legitimate oversight on these matters. I thank you in advance.

P.J. Hardy